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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/868,083	11/19/2001	Zvi Cabantchik	25192	5772

7590
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04/07/2006

EXAMINER

VENCI, DAVID J

ART UNIT	PAPER NUMBER
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1641

DATE MAILED: 04/07/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/868,083	Applicant(s) CABANTCHIK ET AL.	
	Examiner David J. Venci	Art Unit 1641	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on December 28, 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5,8 and 11-22 is/are pending in the application.
- 4a) Of the above claim(s) 11-19 and 22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-5,8,20 and 21 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5,8 and 11-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on December 28, 2005 is entered.

Election/Restrictions

Newly submitted claim 22 is directed to an invention that not linked with the invention originally claimed to form a single general inventive concept under PCT Rule 13.1. Restriction to one of the following inventions is required under 35 U.S.C. 121 and 372:

- I. Claims 1-5, 8 and 20-21, drawn to a method comprising a marker.
- II. Claims 11-14, drawn to a polymer.
- III. Claims 15-19, drawn to a kit.
- IV. Claim 22, drawn to a method comprising calcitonin.

Inventions I-IV, *supra*, do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, unity of invention exists only when the shared same or corresponding technical feature is a contribution over the prior art.

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Here, the special technical feature of Inventions I-IV, *supra*, appears to be a “polymer-conjugated form of a metal chelator” (claim 15).

However, Charlton (US 4,734,375) also teach a “polymer-conjugated form of a metal chelator” (see *e.g.*, col. 10, line 41, “complex of ionophore and ion in the carrier matrix”). Therefore, the technical feature linking Inventions I-IV, *supra*, does not constitute a special technical feature as defined by PCT Rule 13.2, as the special technical feature is not a contribution over the prior art.

Since applicant has received an action on the merits for the originally presented Invention I (i.e. claims 1-5, 8 and 20-21), Invention I has been constructively elected by original presentation for prosecution on the merits.

Accordingly, claims 11-19 and 22 are withdrawn from consideration as being directed to non-elected inventions. See 37 CFR 1.142(b) and MPEP § 821.03.

Currently, claims 1-5, 8 and 20-21 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

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Claim Rejections - 35 USC § 112 – first paragraph

Claims 1-5, 8 and 20-21 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claims contain subject matter that was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Specifically, the amendment filed November 25, 2005, appears to introduce new matter into the disclosure. The added material that is not supported by the original disclosure is as follows:

In claim 1:

A "marker dissociated from said metal ion"

Applicants are required to cancel the new matter in the reply to this Office Action.

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Claim Rejections - 35 USC § 112 – second paragraph

Claims 1-5, 8 and 20-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 1:

In step (a), the prepositional phrases “with a surface coated” and “with a polymer-conjugated iron chelator” are indefinite. The identity of the object(s) of said prepositional phrases is not clear. Whether step (a) requires adding “a surface coated” and/or “a polymer-conjugated iron chelator” to a sample is not clear. The identity of objects subject to “contacting” is not clear.

In step (a), the object “polymer-conjugated iron chelator” is indefinite. Whether said object comprises iron is not clear.

In step (a), the recitation of permissive language “allowing” is indefinite. Whether verbiage subsequent to “allowing” contain required step limitations is not clear.

In step (a), the recitation of the infinitive “to be chelated” is indefinite. Whether the act or process of chelating is completed or performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any, required for performing chelating is not clear.

In step (a), the overall purpose of “allowing the non-bound iron in the sample of biological fluid to be chelated by said polymer-conjugated iron chelator” is indefinite in view of step (b), wherein “said polymer-conjugated metal chelator chelates said metal ion”. The purpose of causing a chelator to chelate iron in step (a), only to subsequently cause said chelator to release iron in step (b) is not clear. One or more essential step(s) providing a purpose for “allowing the non-

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bound iron in the sample of biological fluid to be chelated by said polymer-conjugated iron chelator" appears omitted. See MPEP § 2172.01.

In step (b), the prepositional phrases "with a complex comprising a marker bound" and "to a metal ion" are indefinite. The identity of the object(s) of said prepositional phrases is not clear. Whether step (b) requires adding "a complex comprising a marker bound" and/or "a metal ion" to the sample and/or surface is not clear. The identity of objects subject to "contacting" is not clear.

In step (b), the phrases "said surface with a complex" and "said polymer-conjugated metal chelator" lack antecedent bases.

In step (b), the recitation of the infinitive "to thereby dissociate" is indefinite. Whether the act or process of dissociating is completed or performed, or merely intended, is not clear. The identity of object(s) and/or step(s), if any, required for performing dissociating is not clear.

In step (b), the overall purpose of causing "said marker [to dissociate] from said metal ion" is indefinite in view of step (a) "allowing the non-bound iron in the sample of biological fluid to be chelated by said polymer-conjugated iron chelator". The purpose of simultaneously causing formation of iron—marker and iron—polymer-conjugated iron chelator complexes is not clear. Whether formation of iron—marker complexes confounds "determining an amount of said marker dissociated from said metal ion" in step (c) is not clear. Whether formation of iron—marker complexes confounds "determining the concentration of the non-bound iron" in step (c) is not clear.

In step (c), the phrase "said marker dissociated" lacks antecedent basis.

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In step (c), the term "thereby" is indefinite. The identity of object(s) and/or step(s) referenced by "thereby" is not clear.

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Claim Rejections - 35 USC § 103

Claims 1-2, 5 and 20-21 are rejected under 35 U.S.C. 103(a) as being unpatentable over Tabacco *et al.* (US 4,703,015) in view of Charlton (US 4,734,375).

Tabacco *et al.* describe a method for determining the concentration of iron in a sample of biological fluids (see Abstract, "determination of the ferric iron content of serum") comprising:

- a) contacting (see col. 3, line 47, "addition") the sample (see col. 3, lines 47-48, "biological fluid") with a polymer-conjugated (see col. 2, lines 65-66, "polyoxyalkylenethers") iron chelator (see col. 3, line 47, "chromogenic fluid");
- b) contacting with a marker (see col. 3, lines 59-60, "colorimetric reagent") bound to a metal ion (see col. 2, line 63, "salified")
- c) determining an amount of said marker (see col. 3, line 63, "reading of the optical density"), thereby determining (see col. 3, line 65, "subtraction") the concentration of iron.

Tabacco *et al.* do not describe a method incorporating "a surface coated" or a "surface with a complex".

However, Charlton describes a "surface coated" or a "surface with a complex" (see e.g., col. 10, line 41, "complex of ionophore and ion in the carrier matrix").

It would have been obvious for a person of ordinary skill in the art to adapt the method for determining iron, as described by Tabacco *et al.*, to include "a surface coated" or a "surface with a complex" because Charlton discovered that such surface-based methods allow for "simple, fast analysis" (see col. 4, line

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18), requiring users to “merely contact the sample with a dip-and-read test strip or device” (see col. 4, lines 21-22).

Claim 3 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tabacco *et al.* (US 4,703,015) and Charlton (US 4,734,375), as applied to claims 1 and 2, and further in view of Yegorov *et al.*, 15 FREE RADIC. BIOL. MED. 565 (1993).

Tabacco *et al.* and Charlton describe a method for determining the concentration of iron as substantially described, *supra*, and incorporated herein.

Tabacco *et al.* and Charlton do not teach a method incorporating “desferrioxamine”.

However, Yegorov *et al.* describe a method incorporating “desferrioxamine” (see Title, “desferal”).

It would have been obvious for a person of ordinary skill in the art to use the method for determining the concentration of iron, as taught by Tabacco *et al.* and Charlton, with “desferrioxamine” because Yegorov *et al.* discovered that accurate determination of non-bound metal iron requires a determination of both Fe(III) and Fe(II) simultaneously (see p. 568, col. 2, first sentence) and that desferrioxamine is capable of determining as little as 22 μ M of iron (see p. 572, paragraph bridging col. 1-2).

Claim 4 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tabacco *et al.* (US 4,703,015) and Charlton (US 4,734,375), as applied to claim 1, and further in view of Guire & Chudzik (US 4,826,759).

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Tabacco *et al.* and Charlton describe a method for determining the concentration of iron as substantially described, *supra*, and incorporated herein.

Tabacco *et al.* and Charlton do not teach a method incorporating a "multiwell plate."

However, Guire & Chudzik describe a "multiwell plate" (see Fig. 4) for metal ion determinations (see col. 4, line 23).

It would have been obvious for a person of ordinary skill in the art to use the method for determining the concentration of iron, as taught by Tabacco *et al.* and Charlton, with a multiwell plate because Guire & Chudzik discovered a device that is "rapidly used to indicate the presence, and, if desired, to approximate the amount, of a particular analyte" and is "simple to operate, and can be used generally in the field by non-technical personnel having a minimum of training" (see col. 14, lines 1-16).

Claim 8 is rejected under 35 U.S.C. 103(a) as being unpatentable over Tabacco *et al.* (US 4,703,015) and Charlton (US 4,734,375), as applied to claims 1 and 5, and further in view of Breuer *et al.*, 268 Am. J. PHYSIOL. C1354 (1995).

Tabacco *et al.* and Charlton describe a method for determining the concentration of iron as substantially described, *supra*, and incorporated herein.

Tabacco *et al.* and Charlton do not teach a method incorporating "calcein".

However, Breuer *et al.* teach the use of calcein (see Abstract, "calcein") in iron assays (see Title).

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It would have been obvious for a person of ordinary skill in the art to practice the method for determining the concentration of iron, as taught by Tabacco *et al.* and Charlton, with calcein because Breuer *et al.* discovered that Fe(II) caused 46% fluorescence quenching at a 4:1 iron:calcein ratio and "virtually complete" quenching at higher ratios (see p. C1356, col. 2). In addition, Breuer *et al.* discovered that Fe(III) caused "very rapid and potent" quenching when FeCl₃ is dissolved in distilled water. A person of ordinary skill in the art may interpret these results as an indication that calcein is a favorable indicator of iron concentration and, thus, would serve well in an assay for iron in a sample of serum or other biological fluids.

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Response to Arguments

In prior Office Action, claims 1-5, 8-9 and 20-21 were rejected under 35 U.S.C. 103(a) as being unpatentable over various combinations of teachings from Skold *et al.* (US 5,334,513), Breuer *et al.*, 268 AM. J. PHYSIOL. C1354 (1995), Yegorov *et al.*, 15 FREE RADIC. BIOL. MED. 565 (1993), and Guire & Chudzik (US 4,826,759).

In response, Applicants amend independent claim 1 and provide argumentation pertaining thereto.

Applicants' arguments have been carefully considered and a fully persuasive and sufficient to overcome the aforementioned claim rejections. Accordingly, these rejections are withdrawn.

Further discussion of the teachings of Skold *et al.* and Breuer *et al.* has been rendered moot.

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Conclusion

No claims are allowed at this time.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David J. Venci whose telephone number is 571-272-2879. The examiner can normally be reached on 08:00 - 16:30 (EST). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Long Le can be reached on 571-272-0823. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

David J Venci
Examiner
Art Unit 1641

djv


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